IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO EASTERN DIVISION

THE OHIO WILLOW WOOD COMPANY,

v.

Plaintiff,

Case No. 2:05-cv-1039

JUDGE EDMUND A. SARGUS, JR.

MAGISTRATE JUDGE TERENCE P. KEMP

ALPS SOUTH CORPORATION,

Defendant.

OPINION AND ORDER

Plaintiff The Ohio Willow Wood Company ("OWW") filed this patent infringement action against Defendant Alps South Corporation ("Alps") alleging that Alps is infringing OWW's exclusive rights under U.S. Patent No. 6,964,688 (the "688 Patent") for a "Tube Sock-Shaped Covering." This matter is before the Court on Plaintiff's Motion for Preliminary Injunction (Doc. 41) and Defendant's Renewed Motion to Stay (Doc. 59).

For the reasons that follow, the Court hereby **DENIES** Plaintiff's Motion for Preliminary Injunction (Doc. 41) and **DENIES** as most Defendant's Renewed Motion to Stay (Doc. 59).

I. Background

Both OWW and Alps manufacture and sell a variety of liners used with prosthetic devices. Alleging that several of Alps' liners infringe the 688 Patent, OWW brought this action in November 2005. Alps denies that its products infringe the 688 Patent and asserts that, in any case, the 688 Patent is invalid and unenforceable. In late 2006, Alps requested and was granted a reexamination of the 688 Patent. This case was stayed on February 9, 2007 pending the conclusion of the reexamination. Alps requested further reexaminations of the 688 Patent in March 2007, January 2008, and January 2009. For each of the first three reexaminations, the PTO issued an office action modifying the 688 Patent. On February 6, 2009, when the PTO had

not yet granted Alps' request for a fourth reexamination, the Court granted OWW's motion for relief from stay. The PTO granted Alps' request for a fourth reexamination in April 2009, and Alps renewed its motion to stay (Doc. 59). This Court conducted a hearing on OWW's motion for a preliminary injunction from April 27 to May 1, 2009. Then, on July 19, 2009, after the parties had filed their post-hearing briefs on the motion for a preliminary injunction, the PTO issued an office action on the fourth reexamination (the "Office Action"), rejecting every claim of the 688 Patent. The Court now considers Plaintiff's Motion for Preliminary Injunction and Defendant's Renewed Motion to Stay in light of the Office Action as well as the other evidence presented by OWW and Alps.

II. Analysis

The Court may "grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable."

35 U.S.C. § 283. District courts have "broad discretion . . . to determine whether the facts of a case warrant the grant of an injunction and to determine the scope of the injunction." *Joy Techs.*v. Flakt, Inc., 6 F.3d 770, 772 (Fed. Cir. 1993) (citing Ortho Pharm. Corp. v. Smith, 959 F.2d 936, 945 (Fed. Cir. 1992)).

As in other cases, courts grant preliminary injunctions in patent cases based on the patentee's showing of four factors: (1) reasonable likelihood of success on the merits, (2) irreparable harm in the absence of an injunction, (3) a balance of hardships in the patent holder's favor, and (4) an injunction's favorable impact on the public interest. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001) (citing *Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1555 (Fed. Cir. 1994)). Generally, "[t]hese factors, taken individually, are not dispositive; rather, the district court must weigh and measure each factor

against the other factors and against the form and magnitude of the relief requested."

Amazon.com, 239 F.3d at 1350 (citing Hybritech, Inc. v. Abbott Labs., 849 F.2d 1446, 1451 (Fed. Cir. 1988)). The first factor, likelihood of success on the merits, however, can be dispositive: "a movant is not entitled to a preliminary injunction if he fails to demonstrate a likelihood of success on the merits." Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd., 357 F.3d 1319, 1325 (Fed. Cir. 2004) (citing Amazon.com, 239 F.3d at 1350).

A. Reasonable Likelihood of Success on the Merits

To avoid a showing of likelihood of success, and thereby avoid the grant of a preliminary injunction, "a defendant need not prove actual invalidity," but rather "must put forth a substantial question of invalidity to show that the claims at issue are vulnerable." *Erico Int'l Corp. v. Vutec Corp.*, 516 F.3d 1350, 1354, 1356–57 (Fed. Cir. 2008).

Contending that Claims 1 and 2 of the 688 Patent are invalid for anticipation or obviousness, Alps presented evidence of certain prior art and published references. In its Office Action rejecting every claim of the 688 Patent, the PTO also found that Claims 1 and 2 are unpatentable as obvious under 35 U.S.C. § 103(a) by reason of certain patents and references. Notably, the PTO rejected Claims 1 and 2 as invalid based on some of the same references presented to this Court by Alps: (i) the Klasson patent and (ii) the Single Socket Gel Liner, as described by the Comfort Zone Advertisement and the testimony of Jean-Paul Comtesse.

(i) <u>Klasson Patent No. 4,923,474</u>. Alps presented evidence, and the PTO agreed in its Office Action, that the Klasson patent explicitly discloses every element of Claim 1 of the 688 Patent except for the fabric layer. (Defs.' Br. 31–33; Hr'g Tr. 510–14; Office Action at 21–22.) The PTO found that Klasson disclosed a "radially elastic but axially inelastic" layer, making the use of fabric obvious in light of the Lerman patent. (Office Action at 21.) Alps also

presented evidence that the Klasson patent "taught" fabric, or that the use of fabric would be obvious in light of other patents. (Hr'g Tr. 512–14.) Alps also presented evidence, and the PTO agreed, that Klasson discloses each element as to Claim 2, rendering that claim invalid as well. (Hr'g Tr. 516–17; Office Action at 22.)

(ii) <u>Single Socket Gel Liner ("SSGL")</u>. Alps presented evidence, including testimony of Jean-Paul Comtesse and an SSGL advertisement in the January 1, 1995 issue of O&P Business News ("Comfort Zone Advertisement"), that the SSGL anticipated the claims of the 688 Patent. (Alps Post-Hr'g Br. 25–30; Def. Exs. 3, 7; Hr'g Tr. 307–17, 366–76, 656–657; Comtesse Dep. 71–72.) The PTO agreed with Alps that the SSGL, in combination with certain other patents, anticipated or rendered obvious both Claim 1 and Claim 2 of the 688 Patent. The PTO found that Claim 1 was invalid in view of the Comfort Zone Advertisement as discussed in Jean-Paul Comtesse's testimony and either (a) Chen Patent No. 5,633,286 or (b) Shimizu Patent No. 4,990,556 and the Eva-Glory website. The PTO found that the above references also invalidated Claim 2 of the 688 Patent when viewed with (a) Pohlig Patent No. 5,507,836 or (b) Peterson Patent No. 2,202,598. (Office Action 41, 47–48.)

While the Office Action is not dispositive of OWW's motion, it is directly relevant to the issue of whether Alps has raised a substantial question of validity; other courts have consistently denied motions for a preliminary injunction in the face of an initial office action rejecting the patent. See Avery Dennison Corp. v. Alien Tech. Corp., No. 08-cv-795, 2009 U.S. Dist. Lexis 22467, *23–24, 2009 WL 773825 (N.D. Oh. March 18, 2009); Power Integrations, Inc. v. BCD Semiconductor Corp., No. 07-633, 2008 U.S. Dist. Lexis 108333, *25–33, 2008 WL 5069784, at

¹ In fact, even the grant of an application for reexamination has been found to be "probative to the issue of whether defendants have raised a substantial question of validity." *Pergo, Inc. v. Faus Group, Inc.*, 401 F. Supp. 2d 515, 524 (E.D.N.C. 2005).

*7 (D. Del. Nov. 19, 2008); *DUSA Pharms., Inc. v. River's Edge Pharms., LLC.*, No. 06-1843, 2007 U.S. Dist. Lexis 16005, 2007 WL 748448 (D.N.J. March 6, 2007).

In *Avery Dennison*, after noting that the PTO had "addressed [the] very question" of the patent's validity, the court explained:

There is . . . some practical appeal to the argument that the Court should assess the validity of the patent independent of PTO actions taken as a matter of course. "Substantial question," however, is a relatively low standard that, as noted in *Erico*, merely requires [the defendant] to engender "doubt" regarding the validity of the '596 patent. Under the circumstances of this case, the PTO's initial action rejecting Claim 1 of the '596 patent as anticipated by [prior art] is sufficient to satisfy that standard.

Avery Dennison, 2009 U.S. Dist. Lexis 22467 at *18, *21 (citing Erico Int'l Corp. v. Vutec Corp., 516 F.3d 1350, 1356–57 (Fed. Cir. 2008).

In *Power Integrations*, the court denied a preliminary injunction where the PTO had rejected a patent claim based on the same three prior art references that the defendant contended anticipated that claim. *Power Integrations*, 2008 U.S. Dist. Lexis 108333 at *24. The court found that the defendant had raised a substantial question regarding the validity of the patent claim and that the plaintiff had failed to show that the defendant's challenge lacked substantial merit. The court noted, "[a]s matters currently stand, the PTO has rejected claim 1 . . . If the PTO adheres to this position, [the plaintiff] will not have any property right with respect to claim 1 . . . The possibility that the PTO will adhere to its current position raises a substantial question as to validity." *Id.*, 2008 U.S. Dist. Lexis 108333 at *26–27.

In DUSA Pharmaceuticals, the district court dissolved a previously imposed preliminary injunction after the PTO granted a reexamination and rejected every claim in the patent at issue. The court found that the defendant had "met its burden of demonstrating a changed circumstance that raises a substantial question of validity . . . justifying dissolution of the preliminary injunction" because the plaintiff had "not shown that the validity question raised by the

reexamination order and the Office Action lack[ed] substantial merit." DUSA Pharms., 2007 U.S. Dist. Lexis 16005 at *10.

OWW points out that in the above cases, the office action was issued as to a first request for reexamination, and did not follow an extensive reexamination process such as in this case. (OWW July 10, 2009 Br. 6–7.) The 688 Patent's lengthy reexamination process has, however, resulted in amendments to the 688 Patent. More importantly, the Office Action shows that the PTO found a substantial question as to the patent's validity regardless of prior reexamination proceedings.

The Court finds that Alps has presented colorable arguments regarding the invalidity of the 688 Patent and that the PTO's current rejection of the patent claims significantly supports those arguments. Moreover, OWW has not shown that the validity question raised by Alps' evidence and the Office Action lacks substantial merit. Based on Alps' colorable arguments and the PTO's current rejection of the 688 Patent, the Court finds that there is a substantial question as to the validity of the 688 Patent and OWW therefore has not shown a reasonable likelihood of success on the merits.

Because OWW has not shown a reasonable likelihood of success on the merits and therefore is not entitled to a preliminary injunction, *Nat'l Steel Car*, 357 F.3d at 1325, the Court need not consider the remaining three factors. As discussed below, however, even if OWW had shown a reasonable likelihood of success on the merits, the remaining three factors do not support the grant of a preliminary injunction.

B. <u>Irreparable Harm</u>

Because OWW has not "clearly establishe[d]" likelihood of success on the merits "by making a 'clear showing' of both validity and infringement," it is not entitled to a rebuttable

presumption of irreparable harm. *See Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001). Rather, OWW must demonstrate that it will be irreparably harmed in the absence of an injunction.

OWW asserts that Alps' alleged infringement has resulted in, and continues to result in, unrecoverable damages (due to Alps' inability to pay) as well as lost sales and price erosion in the market. (OWW Post-Hr'g Br. 20–21.) Alps' president, Dr. Aldo Laghi, testified that Alps "probably" could not satisfy a hypothetical judgment of \$16 million in this case, calculated by multiplying 160,000 liners by \$100 per liner. (Hr'g Tr. 261.) OWW presented evidence that OWW has not raised prices of Alpha Liners since 1999, allegedly due to competition (Tr. 78–79), and that since January 2007, OWW has offered rebate programs to certain distributors (Tr. 183–84), effectively lowering the average selling price of its liners by approximately 14% (Tr. 196). OWW presented evidence that it instituted these rebates in response to lower-priced competition, including from Alps. (Pierson Decl., Mot. Ex. O.) OWW also presented evidence that OWW's liner sales increased significantly from 1996 to 2001 and then dropped in 2002, and that sales trends were mixed from 2002 to 2008. (See Hr'g Tr. 71–76.) After the 688 Patent was issued in 2005, sales decreased in 2006 and then increased in both 2007 and 2008. (Id.)

Price erosion, loss of profits, and loss of market share can constitute irreparable harm.

Altana Pharma AG v. Teva Pharms. USA, Inc., 566 F.3d 999, 1010 (Fed. Cir. 2009) (citing Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1382 (Fed. Cir. 2006)). OWW's sales appear to have been unsteady since 2002. However, the only evidence of price erosion or lost sales occurring after the patent was issued in 2005 is OWW's institution of rebate programs in 2007—and the evidence suggests that these rebates were instituted in response to competition in general, including but not limited to Alps' allegedly infringing products. (Pierson Decl., Mot.

Ex. O (declaring that OWW felt pressure to lower its liner prices "[b]ecause of the lower prices of other prosthetic liners in the market, including Alps' liners").)

The Court finds that the evidence presented on irreparable harm does not weigh significantly in favor of either party.

C. Balance of Hardships

OWW asserts that it suffers hardships including lost profits and deprivation of its patent rights, and contends that "an injunction would not cause substantial harm to Alps." (Mot. at 2.) The Court finds otherwise. Alps' president, Dr. Aldo Laghi, testified that liner sales constitute 80-85% of Alps' revenue. (Hr'g Tr. 219, 388.) Not surprisingly given that number, Dr. Laghi also testified that a preliminary injunction would cause Alps to shut down and prevent it from being able to continue to defend against this litigation. (Hr'g Tr. 388.) Even assuming that OWW suffers lost profits and deprivation of its patent rights, the Court finds that the balance of hardships weighs in Alps' favor.

D. Public Interest

Alps asserts that OWW is attempting to stop all competition in the marketplace, which Alps contends is clearly against the public interest. However, a plaintiff's efforts to enforce a valid patent are not against the public interest merely for the reason that the plaintiff attempts to limit competition; rather, the purpose of patent law is to give the patent holder a limited monopoly on its invention.

OWW, on the other hand, asserts that public policy favors the protection of patent rights and the prevention of abuse of the patent reexamination process. According to OWW, Alps used the patent reexamination process to prolong its infringement, as allegedly demonstrated by the extensive waits between reexamination applications despite Alps' alleged prior possession of the

relevant information. The Court is troubled by the prolonged reexamination process in this case, particularly when Alps may have requested reexaminations long after it apparently gained possession of the relevant information. The reexamination process has, however, resulted in amendments to the 688 Patent and, most recently, an Office Action rejecting all claims of the 688 Patent. While Alps may have moved more quickly through the process, the results suggest that Alps' requests for reexamination had merit.

Finally, the Court finds that both parties offer products that improve their customers' quality of life, and granting a preliminary injunction will not benefit the consuming public. The Court finds that the public interest factor does not weigh in favor of granting a preliminary injunction.

IV. Conclusion

For the reasons discussed above, the Court **DENIES** Plaintiff's Motion for Preliminary Injunction (Doc. 41) and **DENIES** as moot Defendant's Renewed Motion to Stay (Doc. 59).

IT IS SO ORDERED.

DATED

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EDMUND A, SARGUS, JR.
UNITED STATES DISTRICT JUDGE